Human Fertilisation & Embryology Authority

Our strategy

2025-2028

Our vision

We want to ensure a well-regulated fertility sector that is trusted by patients and the wider public, that we provide information that is helpful for patients in making treatment choices, and that biosciences that lead to innovations in treatment can flourish within an ethical framework.

Our vision is for:

Regulating for confidence:

- Safe treatment
- Right information
- Supported innovation

This vision recognises the changing UK fertility landscape, and the challenges this presents, both for patients making difficult treatment choices, and for clinics and the HFEA in ensuring the sector is well regulated and that treatment is safe and well evidenced.

2028 marks the 50th anniversary of the first baby born from IVF and the UK regulatory framework has played a key role in ensuring that fertility treatment in this country is safe and of a high quality. But we cannot be complacent.

By 2028 the fertility sector we regulate will be very different from the one that existed when we were set-up in 1991. Many elements of advice are offered online, often from outside the UK, and the distinctions between fertility ‘lifestyle advice’ and medical advice are becoming increasingly blurred. Over time, more diagnostic tests will be informed by AI, and personalised genetic testing is likely to be more commonplace. Some patients may view these developments as positive, providing greater choice and convenience while others may feel unsure about where to go for advice and how to trust the different sources of information.

The next few years are also likely to see significant new developments in scientific research bringing the possibility of new treatment options. Research on embryo models and in vitro derived gametes is now moving fast. The UK has real strengths in bioscience and decisions need to be made on whether and how best to regulate such developments.

The HFEA will need to change and adapt to ensure it remains effective, since the regulatory regime was designed for a world where all treatment was provided in a physical licensed clinic. Online advice and diagnostic tests require a different kind of regulation, elements of which will require a change in the law. The HFEA has a statutory duty to provide information to help patients make informed choices about their treatment options, but we will need to go further. And while inspection will still have a vital role in ensuring high quality services, greater use of data can also inform regulatory action.

As the fertility sector changes over the coming years, we want patients who are seeking a longed-for family to continue to have safe, high-quality, fertility treatment. And we want clinics, researchers and the wider public to have confidence that our regulation can meet the demands of changing times.

Future challenges and priorities

Key challenges that have informed the Authority's consideration of strategic priorities include:

- The fertility sector is changing – it is increasingly commercial, increasingly technology driven and increasingly providing certain services online. This presents patients with new choices (and new dilemmas) which the existing regulatory model was not designed for.
- Access to fertility treatment – some people are delaying trying to start a family and if they have difficulty conceiving, they are finding it hard to access NHS services, while others are excluded from NHS funding.
- Donation is a growing issue for the HFEA and fertility sector, as more people access the HFEA register and interest grows.
- Scientific innovation is now pushing against what is currently lawful in the UK. Obstacles could threaten advances that could help patients and the UK's reputation in biosciences.
- The 1990 Human Fertilisation and Embryology Act is out of date in some respects and requires modernisation.

Following our public consultation in 2023[1] on reforming the HFE Act, we made a range of proposals that we believe would improve patient care and maintain the UK's position as a country where scientific and clinical innovation can flourish. In summary, we have recommended the following:

Patient safety and best practice: the Act should include an over-arching focus on patient protection, and the HFEA should have a broader and more proportionate range of regulatory enforcement powers.

Access to donor information: the Act should enable the removal of donor anonymity from birth, and clinics should be required to inform donors and recipients of the potential for donor identity to be discovered through, for example, DNA testing websites or social media.

Consent: the consent regime in the Act should be overhauled, with a requirement for automatic record-sharing between clinics and the NHS (with the option for patients to opt out).

Scientific developments: there should be greater discretion to support innovation in treatment and research, and the Act should be future-proofed so that it is better able to accommodate future developments and new technologies.

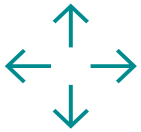
It is important to recognise that if parliamentary time is made available to consider changes to the Act within the lifespan of this strategy, that this would require substantial support from the HFEA. If this occurs, we would reprioritise the objectives in this strategy.

In addition, the Government's 10-year plan for health is expected to be published shortly after this strategy, and we will work to ensure that our work aligns with that plan as needed.

[1] See **Modernising fertility law | HFEA**

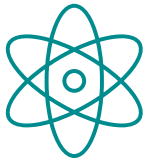
Our strategy

Our strategic ambitions for 2025-2028 are summarised across two themes, set out in below:



Regulating a changing environment

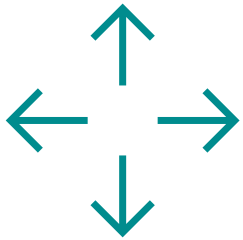
1. To effectively regulate a changing fertility sector.
2. To continue to increase the availability and benefit of our data for patients, clinics and researchers.
3. To ensure that the HFEA responds well to issues related to donation.
4. To make a difference on issues that matter to patients.



Supporting scientific and medical innovation

5. To ensure the safe regulation of emerging new science and technology, under a clear ethical framework.
6. To prepare for the ways in which AI and its future potential is likely to impact on the sector and the HFEA.
7. To inform and advise Government in relation to new developments and their regulation.

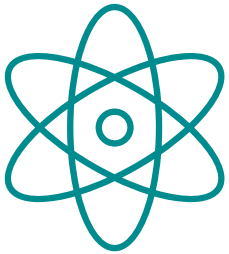
Regulating a changing environment



Objectives	We want	We will
1. To effectively regulate a changing fertility sector.	To maintain public confidence in the safety of the UK fertility sector.	Conduct our regulatory work with fertility clinics in an effective, efficient, consistent and transparent manner, publishing outcomes on our website and reducing the regulatory burden where possible. Provide assurance for patients that the UK fertility sector is well regulated, and provides high quality care, regardless of the choice of clinic. Implement the outcome of our fees review, to ensure the HFEA's regulatory activities continue to be adequately funded.
	To bring together our inspection and clinical governance information with other internal data sources to help us to regulate better.	Enhance our regulatory capability and tools. Make the inspection process more streamlined and efficient.
	Wider regulatory powers to allow us to act further in the patient's interest.	Through our law reform work, continue to make the case for enhanced regulatory powers to ensure effective patient protection and safety in all aspects of fertility treatment including those offered online.
2. To continue to increase the availability and benefit of our data for patients, clinics and researchers.	Patients and others to have confidence that they can access trusted, clear data when navigating the fertility service landscape.	Make improvements to the HFEA website to make more information more readily available. Improve the Choose a Fertility Clinic patient and inspection ratings system. Develop criteria and an HFEA 'trust mark' to help patients identify licensed and regulated sources of treatment.

		Improve the reach of our data so that patients can also have access via other online sources. Develop our internal systems to work towards a single source of information model for our data. Improve data availability for researchers.
3. To ensure that the HFEA responds well to issues related to donation.	To continue to provide accurate and timely information to those affected by donation and making Opening the Register (OTR) requests. To address the implications that arise in relation to the use of donors in treatment.	Continue to develop and monitor our systems to streamline and improve the efficiency of the OTR process. Produce effective communications and clear policy responses.
4. To make a difference on issues that matter to patients.	To speak up for patients on issues such as equality of access to fertility treatment in relation to family type, socio-economic status, ethnicity, or geographical location.	Continue to highlight issues relating to inequality of access to fertility treatment and use our Register data, patient survey and publications to provide evidence. Use our authoritative voice and evidence to inform policy makers. Speak up for patients using our data, expertise and our voice to inform and advise policymakers and legislators in relation to regulatory issues. Work collaboratively with stakeholders and other parts of the healthcare system with a shared interest, for example in relation to inequalities or legislative reforms, and wider Government initiatives on health priorities and women's health.

Supporting scientific and medical innovation



Objectives	We want	We will
5. To ensure the safe regulation of emerging new science and technology, under a clear ethical framework.	To ensure that the barriers to entry for new treatments and technologies are proportionate.	Lead policy formation and the development of regulatory criteria in response to new treatment advances and scientific developments.
	Establish whether new developments (for example new embryo models, artificial gametes) should be brought within a clear regulatory framework.	Work with stakeholders and the government towards ensuring emerging areas are safely regulated.
6. To prepare for the ways in which AI and its future potential is likely to impact on the sector and the HFEA.	Patients and clinic staff to be confident in AI tools as they are deployed.	Work with the sector, professional bodies and other regulatory bodies while ensuring that the way AI is deployed in clinics is patient-centred, evidence-based and safe. Develop our regulatory and inspection approach to take account of AI usage and consider how we can mitigate any risks effectively.
	The HFEA to make best use of developments in AI to make our work more efficient and effective.	Through our IT development activities, work towards a ‘single view’ model of our data so that we are able to make use of AI and automation to streamline certain administrative tasks.
7. To inform and advise Government in relation to new developments and their regulation.	A new legislative framework that allows the UK to maintain its reputation as a leading jurisdiction for fertility biosciences.	Speak up for patients, using our data and our voice to inform and advise policymakers and legislators in relation to new bioscience developments and their regulation. Work to ensure that changes to the Act are made in such a way as to build in some degree of ‘future proofing’, so that future new developments can be regulated effectively without requiring changes to the law on each occasion.

2 Redman Place

London

E20 1JQ

E enquiriesteam@hfea.gov.uk

W: www.hfea.gov.uk